TITLE: **RECLASSIFICATION PETITION: Lateral Mass and Pedicle Screw Spinal Systems (cervical spine uses)**

EXECUTIVE SUMMARY

SPONSOR: **Orthopedic Surgical Manufacturers Association (OSMA)**

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1. BACKGROUND AND REGULATORY HISTORY

The Orthopedic Surgical Manufacturer's Association (OSMA)[1] has filed a reclassification petition ("Petition") to classify unclassified screw use in the lateral masses and pedicles of the cervical spine to Class II with application of general and special controls to assure their safety and effectiveness. The published clinical literature provides adequate information to demonstrate the effectiveness and to define the potential risks of these devices, which may be characterized by a generic description. The types of potential risks with lateral mass and pedicle screws in the cervical spine are the same as those that occur with the same or similar devices for other spinal applications. Class II designations have been adequate to assure the safety and effectiveness of these devices.

Cervical implants currently designated as Class II devices include (FDA product code, Code of Federal Register (CFR) and definition):

Posterior:
- NQW 21 CFR 888.3050 – Plate, Laminoplasty, Spinal Interlaminal Fixation
- KWP 21 CFR 888.3050 – Spinal Interlaminal Fixation Orthosis
- JDQ 21 CFR 888.3010 – Bone Fixation Cerclage

Anterior:
- KWQ 21 CFR 888.3050 – Spinal Intervertebral Fixation
- ODP 21 CFR 888.3080 – Intervertebral fusion device with bone graft, cervical
- OVE 21 CFR 888.3080 – Intervertebral fusion device with integrated fixation, cervical

Class I or III classifications are not appropriate for lateral mass and pedicle screw use in the cervical spine. The regulatory controls of Class I devices (general controls only) do not allow for device characterization and testing with premarket clearance and the additional controls of Class III devices (premarket approval and reporting, premarket inspection) are not consistent with the potential risk of these devices or the classification of similar devices.

Class II is an appropriate classification as it is defined as a low to moderate risk device with known potential risks, which can be effectively mitigated with Special Controls such as guidance documents and labeling. As noted above, other cervical devices are regulated as Class II devices.

Pedicle screw fixation of the spine has a long history of clinical use. In the early 1960's in Europe, Roy-Camille applied pedicle screws to the lumbar spine for the treatment of fractures. In the United States (U.S.), Harrington was the first to initiate use of pedicle screws in 1969 to reduce and stabilize high grade lumbar spondylolisthesis. For the

[1] OSMA is a trade organization whose membership consists of manufacturers of orthopedic surgical appliances, implants, instruments, and equipment and orthobiologics. Since its inception in 1954, OSMA has actively participated in standards development, product labeling guidelines, international activities, and supported multiple reclassification petitions.

cervical spine, Roy-Camille described the application of pedicle screws in 1985, and Abumi reported the first clinical use in 1994. Lateral mass fixation in the cervical spine was first described by Roy-Camille in 1992. As illustrated by the instructional courses taught by major orthopedic and spine societies, lateral mass and pedicle screw use in the cervical spine has become the standard of care when posterior fixation and fusion are required. These screws have largely replaced earlier cervical fixation methods of wiring, cable and/or hook approaches.

Pedicle screw systems for various spinal indications were first marketed in the U.S. before the 1976 Medical Device Amendments (MDA), as preamendment devices. More than 10 years ago in the July 27, 1998 Federal Register (and as amended May 22, 2001), FDA published a final rule classifying certain previously unclassified preamendment pedicle screw spinal systems for the thoracic, lumbar and sacral spine. Pedicle screws for the following indications are Class II: spondylolisthesis, trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor, pseudarthrosis; and failed previous fusion in skeletally mature patients. Only one indication, degenerative disc disease, is Class III. General and special controls, defined through guidance documents, have provided reasonable assurance of safety and effectiveness of these pedicle screw uses.

With respect to this Petition, various preamendment uses of pedicle screws were not addressed specifically in the 1998 classification and remained unclassified (i.e., FDA product code NKG subject of this petition): cervical spondylolisthesis (all grades and types), cervical spondylolysis, cervical degenerative disc disease, degeneration of the cervical facets accompanied by instability, cervical trauma (fracture and dislocation) and revision of failed previous fusion surgery (pseudarthrosis) of the cervical spine. OSMA is aware of two devices that have received 510(k) clearance from FDA for use of pedicle and or lateral mass screws in the cervical spine for a majority of the indications sought in this Petition. On March 20, 1998, the FDA granted Sofamor Danek USA 510(k) clearance of the Townley Pedicle Screw Plating System (K970599). On June 16, 2008, the FDA granted Medtronic Spinal and Biologics 510(k) clearance of the AXIS® Fixation System for posterior cervical pedicle screw/plate fixation (K062254). The FDA's decision for clearance of the AXIS® Fixation System was based entirely upon a review of retrospective clinical data along clinical outcomes described in the published literature.

The Petition is not intended to imply that all there is to be known about cervical pedicle and lateral mass screws is established, but rather that what we have learned to this point leads to a conclusion that the risks associated with the devices are identified, the benefits outweigh the risks, and that the risks can be controlled by general and special controls to provide a reasonable assurance of device safety and effectiveness. Additionally, Class II classification is consistent with FDA's classification of other pedicle screw spinal systems. Class II classification will result in submission and clearance of devices through FDA's premarket notification process and will provide a mechanism for FDA, users and manufacturers to track reports of malfunction and serious injury through the MDR process. For Class II devices, the framework of FDA's 510(k) clearance process supports submission of a generic type of device, like lateral mass and pedicle screws for cervical uses. Device characterization and performance testing, as defined in various guidance documents, with substantial equivalence to predicate devices results in a mechanism to provide reasonable assurance of the devices' safety and effectiveness.

2. CLINICAL NEED

In the cervical spine, when spinal fixation and fusion are indicated, a majority of the procedures are performed from an anterior approach. According to PearlDiver's estimates (http://www.pearldiverinc.com/pdi/spine.jsp) in the U.S. for 2010, of 261,927 cervical fusion procedures 93.4% (244,708) were anterior and 6.6% (17,219) posterior.

Various posterior pathologies can destablilize the cervical spine and result in neural compression, and/or craniospinal or spinal instability. Correction of the subluxation or malalignment, decompression and stabilization must be performed. Anterior pathologies limited to 1- or 2-vertebral body levels are usually addressed with an anterior approach and those with more than two levels a posterior approach. While the most frequent indication for posterior cervical spine fixation is instability secondary to traumatic injury, posterior stabilization is also utilized in treating non-traumatic causes of instability including congenital, inflammatory, tumors, and degenerative conditions. Most of these conditions involve multilevel and more complex reconstructive needs. The intended outcome of posterior stabilization may be stability with fusion, temporary stabilization, pain control, palliative care, relief and/or prevention of neurologic deficit.

For approximately 100 years, surgeons have applied various surgical techniques to achieve posterior stabilization of the cervical spine. Wiring has the longest history of use, is relatively easy to implement, carries a low risk of neurological or vascular injury, and does not require x-ray guidance (Arnold 2005). It is important to note the differences with relatively safe spinous process wiring versus sublaminar wiring which involves more neurological risk. However, after placement of the wires, halo-vest immobilization is generally prescribed for three months (Sasso 2007). With wiring, even with halo-vest use, non-union rates may be as high as 30% (Harms 2001, Stulik 2007). In addition, halo-vest immobilization often results in significant co-morbidities among elderly and fragile patients.

Lateral mass and pedicle screws have been utilized in cervical stabilization for approximately 20 years. Based on pre-operative assessment of the patient's anatomy, nerve roots, vasculature, number of levels and pathology, surgeons identify the most appropriate treatment options; these include device constructs for the patient consisting of all pedicle screws, all lateral mass screws or a combination of both.

Lateral mass fixation was initially described by Roy-Camille in 1992 (Arnold 2005). Lateral mass fixation originally incorporated plates and later rods, which were contoured to the spine's curvature. In 1985, Roy-Camille described the surgical technique and use of pedicle screws for Hangman's fractures at C2. In 1991, Panjabi published a three-dimensional anatomic study of the human cervical spine. The capacity of the cervical pedicles to accept transpedicle fixation was shown. In 1994, Kotani demonstrated that pedicle screws offered increased stability over conventional anterior and/or posterior constructs when used for 2-column or 3-column instability. In 1994, Abumi (2000) was the first to report transpedicle instrumentation in 13 patients with subaxial cervical trauma. Ludwig (1999) noted that three-column fixation with pedicle screws increased stability and strength, and that the pedicle offered the strongest point of attachment to

the cervical spine. The additional support of halo-vest immobilization is not required with pedicle and lateral mass screws.

3. DEVICE DESCRIPTION

3.1. ATTRIBUTES OF GENERIC DEVICE TYPE

This Petition seeks to reclassify a generic type of device, pedicle and lateral mass screw systems for cervical spine indications. According to 21 CFR 860.3(i), a generic type of device means:

> "a grouping of devices that do not differ significantly in purpose, design, materials, energy source, function or any other feature related to safety and effectiveness, and for which similar regulatory controls are sufficient to provide reasonable assurance of safety and effectiveness".

A generic device definition follows: Cervical pedicle and lateral mass screws are part of multi-component occipito-cervico-thoracic (OCT) devices that allow surgeons to construct an implant system to accommodate the patients' anatomic and physiologic requirements. The multi-component OCT devices consist of an anchor (i.e., occipital, lateral mass, and pedicle screws, and/or hooks) and optional longitudinal members (e.g., plates, rods, and/or plate/rod combinations) and transverse connectors. An interconnection mechanism (e.g., offset connector, nuts, screws, sleeves or bolts) may be utilized. The anchors or screws form the bone-implant interface, the longitudinal members connect the anchoring members, and transverse connectors link the longitudinal members.

The system components are comprised of various standard metals commonly used in the spine including stainless steel, titanium, cobalt chromium alloy and titanium alloy. These systems may be provided either sterile or non-sterile (sterilized by third party before use) and are intended for single use only.

Pedicle and lateral mass screws for the cervical spine have the same characteristics as devices used for the current Class II indications, including those used in the cervical spine and occipito-cervico-thoracic junction (FDA product codes MNI, spinal pedicle fixation; and KWP, Spinal Interlaminal Fixation Orthosis).

3.2. INDICATIONS

With the Petition, as noted in the Supplemental Data Sheet (Section 6.2), the following indication for use is recommended:

Lateral mass and pedicle screw systems are intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion during bone graft healing and fusion mass development and/or to restore the integrity of the spinal column even in the absence of fusion for a prolonged period for the following acute and chronic instabilities of the cervical spine (C1 to T3 inclusive): trauma, including spinal fractures and/or dislocations; instability or deformity; pseudarthrosis or failed previous fusions; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and

degenerative disease of the facets with instability; and tumors. Spinal screw fixation is achieved with posterior pedicle and lateral mass screws implanted from C1 to T3 levels inclusively.

4. CLINICAL EVIDENCE: PUBLISHED LITERATURE

4.1. METHODS AND SELECTED ARTICLES

To characterize the effectiveness and to define the risks associated with cervical lateral mass and pedicle screws, an electronic clinical literature search was conducted for articles published between 1999 to July 23, 2012. Article titles and abstracts were reviewed, and when the abstract did not include information that would exclude the article, the full text article was reviewed. In addition, the bibliographies from the relevant articles were screened to identify additional pertinent articles. Articles were selected if the study included 15 or more subjects had lateral mass and/or pedicle screw use in cervical spine with reports of safety, performance, and/or effectiveness results. Articles were excluded if the cervical fixation construct included other screws in addition to lateral mass or pedicle screws (e.g., transarticular, pars, laminar, or other screws).

From the PubMed search for lateral mass and pedicle screws, a total of 545 titles/abstracts and 87 full text articles were reviewed. From these articles, 51 articles with clinical study results and seven general overview articles were selected. For the 51 studies, the screw constructs included 25 studies with pedicle screws only, 14 with lateral mass only, and 12 with a combination. With the exception of six studies, all studies were single cohort study designs. Six studies included various comparative analyses: 4 compared various placement and/or image guidance techniques and 2 compared lateral mass/pedicle screw constructs to other screw constructs. A majority of the studies included an average follow-up of one or more years. The 51 clinical studies included reports of 2,967 subjects with a variety of clinical indications as follows.

Table 1. Total Number of Patients by Indication

Indication	Total	%
Trauma	1027	34.6%
Instability/Deformity	659	22.2%
Pseudarthrosis/Failed Fusion	46	1.6%
Degenerative	931	31.4%
Tumor	218	7.3%
Other	86	2.9%
Total	2967	100.0%

Degenerative conditions included primarily cervical spondylotic myelopathy (CSM) and/or ossification of the posterior longitudinal ligament (OPLL).

To identify comparative safety and fusion results for cervical fixation methods including cervical cables, hooks and/or wiring methods, which are Class II devices, a second PubMed search was performed for literature published between 1999 to August 1, 2012. Articles were excluded if the cervical fixation construct included screws in the wiring/cable construct or excluded use of any wire/cable, had fewer than 15 subjects, or provided no safety or effectiveness results. A total of 71 titles/abstracts and 12 full text

articles were reviewed, and seven articles were selected. Two of the studies were comparative studies, one retrospective and one a systematic review, with comparisons of various wiring/hook constructs to screw/plates and screw/rods. The other five articles with results from single cohort studies included results on 156 subjects. A variety of clinical indications were represented with approximately 22% trauma, 37% instability/deformity, 27% tumor and 14% degenerative. Average follow-up ranged from 6 to 53 months.

4.2. EFFECTIVENESS/PERFORMANCE

The intended outcome of posterior stabilization may be stability with fusion, temporary stabilization, pain control, palliative care, relief and/or prevention of neurologic deficit. For lateral mass and pedicle screws, results from the published literature are summarized in Table 2 relative to fusion rates and Table 3 for clinical outcomes.

As shown in Table 2, 26 studies reported fusion outcomes with 13 reporting 100% fusion, 11 reporting fusion rates greater than 90% (< 100%) , one reporting 89% and one reporting that fused segments were stable.

Four of the five single cohort studies with results for posterior wiring, cabling or hooks provided fusion rate results with reports of 71%, 93%, 95% and 100%. In addition, Winegar (2010) published a systematic review of the literature based on 34 articles and 799 patients. There were no statistically significant differences between the fusion rates for the four groups (wiring/rod 95.9%, wire/graft onlay 88.3%, screw/plate 94.7%, and screw/rod 93.0%).

Many of the patients, who receive a posterior fusion, have significant instability and consequently seriously compromised neurologic function. As shown in Table 3, 16 studies noted results for neurologic outcomes, and all reported maintenance or improvement in outcomes. Ten studies included results for pain and/or disability, and consistently reported improvement in patient outcomes.

In addition, Winegar (2010) published a systematic review of the literature based on 34 articles and 799 patients and compared results for four construct groups including patients with a variety of indications. The screw/rod group had a higher rate of neurologic improvement ($p<0.0001$) than the other groups (wiring/rod 51.8%, wire/graft onlay 72.9%, screw/plate 72.4%, and screw/rod 81.6%).

These published articles demonstrate that the use of pedicle and lateral mass screws in cervical spine constructs is effective. Benefits of high fusion rates, and improved/preserved neurologic function for patients treated with pedicle and lateral mass screw fixation of the cervical spine were demonstrated consistently. Improvement in pain and function was also noted in studies of lateral mass and pedicle screw studies. Compared to results for hooks, cables and wiring, which are Class II devices, lateral mass and pedicle screws resulted in comparable or higher fusion rates and higher rates of neurologic improvement.

Table 2: Published Literature with Reports of Fusion Rates

Author/Year	N	Indication	Follow-up	Screws		Bone Graft	Fusion	Fusion Definition
				Pedicle	Lateral Mass			
Abumi/2000	164	multi	>2 yrs	C2-C7	--	Not specified	99.4% (163)	homogeneous fusion mass on lateral x-rays and segmental motion < 2 degrees on flex/ext, as well as clear zone around screws.
Arnold/2005	48	trauma	1 yr	C7	C3-C7	Local bone, allograft as necessary	93.8% (45)	lateral and flex/ext x-rays with pseudarthrosis defined as motion greater than 2mm at any point within fused segment
ElMiliqui/2010	15	trauma	32 mos	C2	--	Not specified	100% (15)	lateral and flex/ext x-rays with evidence of healing across the fracture site, no metal failure and no evidence of instability on dynamic views
Goel/2002	160	trauma	42 mos	--	C1-C2	Cortico-Cancellous bone or allograft	100% (160)	no dislocation observed on dynamic radiographs 5 mos post op
Harms/2001	37	multi	5 mos to 2 yrs	C2	C1	Local bone and/or autograft	100% (37)	Not defined
Hasegawa/ 2008	47	multi	59.2 mos	Yes	--	Local bone	97.9% (26)	Not defined
Huang/2003	32	CSM/OPLL	15.2 Mos	--	Yes	Local bone/ DBM	96.9% (31)	Not defined
Isikawa/2008 Fluoroscopy 3D navigation	30 32	multi	41.7 mos 21.2 mos	C2-C7	C2-C7	Not specified	93.1% (27) 93.5% (29)	Not defined
Isikawa/2011	21	multi	13.1 mos	C2-C7	--	Type not specified	90.5% (21)	Homogeneous mass at posterior part of lamina and lateral mass, including facet joint, and clear zone around screws
Jian/2010	29	Instability/ deformity	18 mos	C2	C3	Cortico-Cancellous bone or allograft	100% (29)	CT showed bone bridge formation and dynamic x-ray showed stable reduction of the dislocation with implant failure at 3-6 mos
Katonis/2011	225	CSM	18 mos	--	C3-C6	Local bone/ allograft	97.4% (219)	Pseudarthrosis: motion > 2mm on flexion/extension films
Kotil/2012	45	multi	35.7 mos	C3-C7	--	Iliac crest	100% (45)	Not defined

Table 2: Published Literature with Reports of Fusion Rates

Author/Year	N	Indication	Follow-up	Screws		Bone Graft	Fusion	Fusion Definition
				Pedicle	Lateral Mass			
Lee/2010	27	Instability/ deformity	32.8 mos	C2	C1	Autograft	96% (26)	Bony trabecular continuity and <2mm motion between the segments on flexion/extension.
Li/2008	23	multi	15 mos	C1, C2 lower	lower	Bone granules or iliac crest	100% (23)	Firm bony fusion
Liu/2009	25	multi	16.6 mos	C3-C7	--	Bone graft	Fused segments stable	Flex/ext x-rays intervertebral angles < 2 deg and distance variations between adjacent spinous processes < 2mm.
Muffoletto/ 2000	35	multi	2-3.5 yrs	--	C3-C6	Iliac crest	89% (31)	Pseudarthrosis: motion > 2mm on flexion/extension films
Nakashima/ 2011	84	multi	4.1 yrs	C2-C7	--	Not specified	97.6% (NS)	Flexion/extension radiographs
Oda/2006	32	tumor	12.2 mos	All levels	--	Autograft*	94% (30)	Spinal stability *autograft if life expectancy > 1 yr
Ogihara/2010	23	multi	52.9 mos	C1-T3	--	Iliac crest	100% (23)	Bony union based on dynamic x-rays and CT
Stevens/2009	16	multi	> 6 mos	--	C3-C7	Morselized autograft or allograft	100% (16)	Absence of motion on dynamic imaging, trabecular bone on CT, absence of screw halo or grossly migrated implants
Stulik/2007	24	multi	17.1 mos	C2	C1	Iliac crest and substitute if needed	100% (24)	Bone bridging on lateral x-ray between the posterior and epistropheus arches
Tan/2009	17	trauma	14 mos	C2	C1	Bone graft	100% (17)	Bony union without instability on lateral x-ray
Tofuku/2012	32	trauma	27.6 mos	C2-C7	--	Local bone	100% (32)	Stability on flexion/extension radiographs
Wang/2006	18	multi	> 2 yrs	--	C3-C7	Iliac crest	100% (18)	Bridging bone and < 2 degrees motion on flexion/extension radiographs and CT
Wang/2010	319	instability/ deformity	32.4 mos	C2	C1	Iliac crest	100% (319)	Radiographs with confirmatory reconstructive CT with obvious osseous union between the C1 posterior arch and C2 lamina
Wu/2008	115	multi	14 mos	--	C3-C7	Local bone/DBM	99.1% (114)	Dynamic lateral radiographs

NOTE: Bolded articles are updates since the November 2011 petition.

Table 3: Published Literature with Reports of Clinical Outcomes

Author/Year	N	Indication	Follow-up	Screws		Neurologic	Functional
				Pedicle	Lateral Mass		
Arnold/2005	48	trauma	1 yr	C7	C3-C7	28 with motor injuries: 20 improved and others unchanged	--
Cornefjord/2005	19	trauma	1 yr	C2-C7	C3-C6	Of 11 with no pre-op neuro deficit, 1 developed right arm weakness. Of 8 with pre-op neuro deficit, 2 improved and others unchanged.	--
ElMiliqui/2010	15	trauma	32 mos	C2	--	--	VAS Neck Pain last visit: 1 (0-2)
Goel/2002	160	trauma	42 mos	--	C1-C2	All with quadraparesis or quadriplegia improved	--
Harms/2001	37	multi	5 mos – 2 yrs	C2	C1	0% worse neurologic outcomes	--
Hasegawa/ 2008	58	multi	59.2 mos	Yes	--	Frankel Scale improved at last follow-up	Nape pain improved from 66% pre-op to 16.5% last visit
Houten/2003	38	CSM/ OPPL	7.2 mos	--	C2-T1	96% muscle improvement 97% JOA improvement	Significant improvement in upper and lower extremity function
Huang/2003	32	CSM/ OPPL	15.2 mos	--	Yes	Nurick scores improved. No neurologic deterioration	--
Jian/2010	29	Instability/ deformity	18 mos	C2	C3	JOA: Pre-op: 12.9 improved to 6-mos Post-op: 15.4	Symptoms improved in 92.9% (26/29)
Kim/2007	65	multi	8.8 mos	C2, C7	C1, C3-C6	--	NDI Pre/Last: 38/17 VAS Pain Pre/Last: Neck: 8.2/3.2 Arm: 7.1/2.3
Kumar/1999	25	CSM	47.5 mos	--	Yes	No neurologic deterioration	Myelopathy severity and function: 76% improved and 24% stable
Lee/2010	27	instability/ deformity	32.8 mos	C2	C1	Frankel Scale improvement	VAS Neck: 96% (26/27) improved

Table 3: Published Literature with Reports of Clinical Outcomes							
Author/Year	**N**	**Indication**	**Follow-up**	**Screws**		**Neurologic**	**Functional**
				Pedicle	**Lateral Mass**		
Liu/2009	25	multi	16.6 mos	C3-C7	--	JOA mean improvement: 4.1	NDI Pre/6-mos: 32.96/16.84
Oda/2006	32	tumor	12.2 mos	All levels	--	Frankel Scale: 80% (24/30) with spinal cord lesions improved 89% (16/18) not ambulatory pre-op walked	Pain relief achieved all patients
Ogihara/2010	23	multi	52.9 mos	C1-T3	--	JOA Pre/Last: 7.1/11.3 improved Neurologic deficit (Ranawat): 74% (17/23) improved more than one grade	--
Sekhon 2005	143	multi	22 mos	--	C3-C7	Nurick scores improved 2.3 pre-op to 1.01 last	--
Sekhon 2006	50	CSM	30.1 mos	--	Yes	Nurick scores improved 1.93 pre to 1.21 last	Oswestry Neck Disability improved 24.7 pre to 16.6 last
Tofuku/2012	32	trauma	27.6 mos	C2-C7	--	48.1% improved and none deteriorated	--

NOTE: **Bolded** articles are updates since the November 2011 petition.

4.3. RISKS TO HEALTH

Risks to health related to lateral mass and pedicle screw use in the cervical spine were identified from the published literature, as well as FDA's Manufacturer and User Facility Device Experience (MAUDE) database.

Published Literature: Screw Placement Accuracy

Use of cervical lateral mass and pedicle screws entails the potential risk of vertebral artery (VA), spinal cord and nerve root injury. Anatomic restrictions for pedicle screws include anomalies of the VA artery, varied and small size pedicles with restricted direction for screw insertion, and bone that precludes placement (Abumi 2012, Sciubba 2009, Stevens 2009, Ludwig 1999, Yukawa 2009). Deformity may cause abnormality of the VA, and stenosis or occlusion may exist (Ogihara 2010).

Given these potential procedural risks, a number of studies have been conducted specifically to assess screw placement. A total of 32 studies included a CT post-op assessment of pedicle and/or lateral mass screw placement, and three other studies examined screw placement following various methods of intra-operative guidance.

In the 32 studies summarized in Table 4, rates of satisfactory placement, as well as whether the screw malposition resulted in an adverse event, are noted. Various criteria to assess screw breach or perforation were applied to define "satisfactory" screw placement. Most studies considered no perforation of the pedicle wall or a perforation < 2mm or less than 50% the screw length as satisfactory. Of the 32 studies, 27 reported that the rate of satisfactory placement was greater than 90%. Lower satisfactory placement rates were reported for five studies with rates of 74.7%, 83.0%, 85.2%, 86% and 87.5%. The placement studies did not demonstrate any consistent trend for screw placement accuracy based on the type of visualization during surgery, including free hand, image intensifier/fluoroscopy and computer assisted surgery.

As shown in Table 4, 18 of the 31 studies reporting adverse events reported no adverse events related to screw placement. For the other 13 studies with reports of adverse events (total 25 patient events), the rates by study ranged from 1.1% to 3.7% for nine studies. Three studies had fewer than 20 patients and with one event in each study, the event rates were 5.3%, 5.6%, and 6.7%. One study with 84 patients reported five events (6.0%). The 25 patient events included the following. A total of 16 VA injuries were reported and all resolved intra-operatively with application of bone wax or screw insertion or resulted in transient symptoms. Nine neurologic events were reported; three were transient and six were resolved with screw revision or removal.

Table 4. Published Studies with CT Assessment of Lateral Mass and/or Pedicle Screw Placement Accuracy						
Author/Year	**Number Subjects**	**Number Screws**	**Screws**		**CT Screw Placement Assessment: Satisfactory**	**Subjects**
			Pedicle	**Lateral Mass**		**Adverse Clinical Event***
Alosh/2010	93	170	C2	--	74.7% (127/170)	1.1% (1/93)
ElMiliqui/2010	15	30	C2	--	93.4% (28/30)	6.7% (1/15)
Goel/2002	160	NS	--	C1-C2	--	2.5% (4/160)
Harms/2001	37	NS	C2	C1	100%	0.0%
Mueller/2010	27	47	C2	--	83.0% (39/47)	3.7% (1/27)
Ondra/2006	79	150	C2	--	99.3 (149/150)	2.5% (2/79)
Parker/2009	70	161	C1-C3	--	93.2% (150/161)	1.4% (1/70)
Sciubba/2009	55	100	C2	--	98.0% (98/100)	0.0%
Stulik/2007 lateral mass pedicle	28	 56 56	 C2	C1	 100% (56/56) 94.6% (53/56)	0.0%
Wang/2010 lateral mass pedicle	319	 638 638	 C2	C1	 95.5% (609/638) 92.8% (592/638)	0.0%
Abumi/2000	180	669	C2-C7	--	93.3% (624/669)	1.7% (3/180)
Cornefjord/2005	19	67	C2-C7	--	94.0% (63/67)	5.3% (1/19)
Djurasovic/2005	26	148	C7	C3-C6	94.6% (140/148)	NS
Inoue/2012	94	457	--	C3-C6	90.4% (413/457)	0.0%
Ishikawa/2011	21	108	C2-C7	--	97.2% (105/108)	0.0%
Ishikawa/2010 Fluoroscopy 3D-Fluoro	 30 32	 126 150	 C2-C7 C2-C7	 -- --	 87.3% (110/126) 96.7% (145/150)	3.2% (2/62)
Ito/2008 pedicle lateral mass	 50 50	 176 58	C2-C7 --	-- C2-C7	 97.2% (171/176) 100% (58/58)	0.0%
Kim/2007	65	486	C2, C7	C1, C3-C6	97.5% (474/486)	1.5% (1/65)
Kotil/2012	45	210	C3-C7	--	97.6% (205/210)	0.0%
Lee/2012	48	205	C3-C7	--	85.2% (174/205)	0.0%
Liu/2009	25	150	C3-C7	--	96.0% (144/150)	0.0%
Muffoletto/2000	35	146	--	C3-C6	98.6% (144/146)	0.0%
Nakashima/2011	84	390	C2-C7	--	95.9% (374/390)	6.0% (5/84)
Neo/2005	18	86	C2-C6	--	86.0% (72/86)	5.6% (1/18)

Table 4. Published Studies with CT Assessment of Lateral Mass and/or Pedicle Screw Placement Accuracy						
Author/Year	**Number Subjects**	**Number Screws**	**Screws**		**CT Screw Placement Assessment: Satisfactory**	**Subjects**
			Pedicle	**Lateral Mass**		**Adverse Clinical Event***
Ogihara/2010: C2, C7 C3-C6	23	 41 47	 C2, C7 C3-C6	 --	 100% (41/41) 97.9% (46/47)	 0.0%
Richter/2005 Intensifier	 20	 93	 C3-C7	 --	 91.4% (85/93)	 0.0%
Image guided	32	167	C3-C7	--	97% (162/167)	0.0%
Schaefer/2011	15	72	C2-T4	--	87.5% (63/72)	0.0%
Sekhon/2005	143	1026	--	C3-C6	94.5% (968/1026)	0.0%
Tofuku/2012	32	127	C2-C7	--	96.1% (122/127)	0.0%
Yoshimoto/2009	52	280	C2-C7	--	98.2% (275/280)	0.0%
Yukawa/2009	144	620	C2-T2	--	96.1% (596/620)	1.4% (2/144)
Zhuo/2010	48	NS	lower	--	100%	0.0%

*includes events from probes, drilling and/or screws: vertebral artery injury, bleeding, neurologic

NOTE: **Bolded** articles are updates since the November 2011 petition.

Two additional studies (Lee 2007 and Liu 2010) compared the accuracy of screw placement with various visualization methods. Lee (2007) compared the accuracy of pedicle screw placement at the cervicothoracic junction using the open or freehand method to 2-D and 3-D computer-assisted surgery (CAS) techniques. Pedicle screw placement was at C7, T1 and T2. There were no differences in the rates of pedicle breach, and no screws resulted in a revision. Liu (2010) compared the accuracy of pedicle screw placement in the cervical spine using fluoroscopy, CT-navigation or 3D-navigation. All three methods had high rates of acceptable placement, and there were no differences in results between groups. No complications were reported.

For purposes of comparison of the accuracy of pedicle screw placement in the cervical, thoracic and lumbar spine, a meta-analysis (Kosmopoulos 2007) of the published literature (1966-2006) was reported. Overall, for 12,299 pedicle screws paced in 32 patient studies, the mean and median accuracy of placement were 92.4% and 95.2% respectively with navigation and 82.2% and 90.3% respectively without navigation. For studies focusing on specific levels of the spine, the overall placement rate accuracy was high with and without navigation for all levels of the spine with the highest rates for the cervical spine. The author noted that for all levels of the spine, thorough knowledge of local anatomy, careful pre-op planning and intra-operative visualization or computer guidance, based on the surgeon's preference, are important.

Published Literature: Adverse Events

As with any surgical procedure, adverse events may occur relative to the use of anesthesia, surgical access, or devices and instruments, as well as patient co-morbidities. To characterize the events related to use of cervical lateral mass and pedicle screws, results from 42 studies included assessment of device events (2,080 patients; 38 studies) and/or general medical events (2,216 patients; 38 studies).

The types of risks to health for pedicle and lateral mass screws device events, as reported in the literature, are comparable to other spinal devices (Table 5).

Table 5. Published Studies Lateral Mass and Pedicle Screw Placement: Risks to Health - Device Adverse Events

Total Studies Reporting	38	
Total Number Patients	2080	
Device Adverse Event	**Number**	**%**
Bone fracture (lateral mass or pedicle)	35*	1.7%
Malposition screw	14	0.7%
Loss of correction	12	0.6%
Screw loosening/pull out	30	1.4%
Strut/graft displacement	1	0.0%
Screw breakage/dislodgment	22	1.1%
Rod dislodged	1	0.0%
Plate breakage	1	0.0%
Progressive degenerative change	6	0.3%
Heterotopic ossification	1	0.1%
Pseudarthrosis	11	0.5%

Note: The bone fracture rate is a conservative worse case estimate, as 27 of the 35 events were reported "per screw" not "per patient".

Based on the published literature, the types of risks to health based on other adverse events for pedicle and lateral mass screws are comparable to other spinal devices (see Table 6). The reported rate of re-operation was 2.1% (47/2,216). Note that the reported neurologic events include those related to the surgery and may be related to the surgical procedure or the device. The earlier discussion on screw placement specifically defines neurologic events related to screw malposition.

The VA injuries include report of four additional injuries beyond those described with the placement accuracy studies. Two events were noted without any details, one with no consequence of VA injury, and one where the bleeding was stopped with gauze tamponade. One study reported no cases of VA or neurovascular injury from screw placement; however, six instances of venous plexous bleeding were reported; all resolved with bipolar coagulation, screw insertion and tamponing. In addition, one study (Jian 2010) reported a death from a VA injury where the C2 screw breached the pedicle, and entered the medial portion of the transverse foramen (CT) with VA stenosis and distal thrombosis in the basilar artery (angiography). Jian reported that after surgery the patient was extubated without neurologic deterioration, and six hours later the patient became comatose with respiratory insufficiency. Endovascular thrombolysis failed and the patient expired seven days later. No other deaths related to pedicle or lateral scrws were identified in the published literature.

In addition to the VA and neurologic injuries reported in Tables 4 and 6, Pan (2010) utilized 96 lateral mass screws in C1 and C2 constructs for 48 patients. Venous sinus bleeding was reported for 6.3% (6/96) screws and post-operative numbness for 8.3% (4/48) patients.

Neo (2008) noted that a VA injury can occur with various cervical spine surgery techniques. To assess the occurrence of these injuries, Neo conducted a survey of 29 general orthopedists and seven spine surgeon groups in Japan. In the past five years, the participants reported conduct of 5,641 surgeries: 2,190 were anterior cervical decompression/fusion (ACDF) or foraminotomy, 149 transarticular screws, 204 lateral mass/pedicle screws, nine transarticular screws and 42 tumors (surgery not specified). The overall incidence of VA injuries was very low at 0.14% (8 cases of injury split between anterior and posterior approaches: 3 ACDF, 1 tumor resection, 2 Magerl, 1 foraminotomy, 1 lateral mass screw). No VA injuries were reported for pedicle screw cases.

Table 6. Published Studies Lateral Mass and Pedicle Screw Placement: Risks to Health - Other Adverse Events

Total Studies Reporting	38	
Total Number Patients	2216	
Other Adverse Event	**Number**	**%**
Neurological:		
Upper extremity numbness/pain	6	0.3%
Neuropathic pain	1	0.0%
Nerve root palsy	22	1.0%
Residual paresthesias, shoulder	1	0.0%
Transient paresis	6	0.3%
Muscle weakness	8	0.4%
Dural lesion/violation	9	0.4%
Radiculopathy	13	0.6%
Wound:		
Dehiscence/Debridement	5	0.2%
Delayed wound healing	1	0.0%
Wound hematoma/seroma	6	0.3%
Infection	19	0.9%
Deep wound infection	16	0.7%
CSF leak	15	0.7%
Other:		
Neck pain	7	0.3%
Swallowing disturbance	3	0.1%
Blurred vision	1	0.0%
Blood loss	11	0.5%
Venous plexus bleeding	6	0.3%
Vertebral artery bleeding	4	0.2%
Vertebral artery injury	18	0.8%
Respiratory issue	3	0.1%
Skin irritation	2	0.1%
Iliac crest pain	1	0.0%
Other General Medical	13	0.6%
Death related to procedure and/or device	1	0.0%
Re-operations	47	2.1%

Reports of complications following use of posterior wiring, cabling or hooks follows. Winegar (2010) published a systematic review of the literature based on 34 articles and 799 patients for various indications. The rate of instrument failure was statistically significantly different between construct groups: wiring/rod 13.5% (13/96), wire/graft onlay 100% (14/14), screw/plate 26.7% (8/30), and screw/rod 7.9% (3/38). Garrido (2011) conducted a retrospective study and compared the results of occipitocervical fixation with non-rigid (rod/cable or wire/cable) to rigid (screws with plates or rods) constructs. The rate of patients with a complication was statistically significantly higher in the non-rigid group (48%, 12/25) compared to the rigid group (4%, 2/46).

All five single cohort studies with results for posterior wiring, cabling or hooks provided adverse event results. The rate of neurologic events and re-operations was higher in these patients compared to those treated with lateral mass and pedicle screws (i.e., neurologic: 1.8% screws versus 5.8% wiring/cable; and re-operation: 1.1% screws versus 10.3% wiring/cable).

In summary, placement accuracy rates of lateral mass and pedicle screws in the cervical spine were high, and the results were comparable to screw placement accuracy in the thoracic and lumbar spine. The rate of VA and neurovascular injury was low, and with the exception of one event out of 2,216 surgeries none resulted in serious long term consequences. The rates of device specific events were low. The rate of neurologic, instrument failure and re-operation events for lateral mass and pedicle screws was lower than the cited studies for posterior wiring/cabling.

MAUDE

To demonstrate that the risks associated with pedicle and lateral mass screws for cervical use do not pose an unreasonable risk of injury or illness and that the types of risks are not different than current Class II cervical devices, MAUDE data for the past six years (January 1, 2006 to December 31, 2011) were reviewed for product code NKG (lateral mass and pedicle screws) as well as other Class II cervical devices.

There were no reported events for the two devices cleared for lateral mass and or pedicle screw use in the cervical spine (Medtronic Axis® Fixation System, product code NKG; Sofamor Danek USA Townley Pedicle Screw Plating System) through June 29, 2012).

Events were quantified for current Class II anterior and posterior cervical devices including the following: anterior (interbody fusion cages (ODP), interbody fusion with integrated fixation device (OVE), and plates/screws (KWQ)) and posterior (laminoplasty plates (NQW) and hooks/wire (KWP), wiring (JDQ)). The product codes for KWQ, JDQ and KWP include cervical as well as other spinal vertebra; however, for purposes of an "orders of magnitude", worst case comparison, it was assumed that all events were related to the cervical spine. From 2006 to 2011, there were 2,431 anterior and 2,962 posterior events. For an estimation of event rates, according to PearlDiver market statistics (Attachment E, Petition) from 2006 to 2011, there were 1,413,244 anterior cervical fusion procedures and 98,361 posterior cervical fusions. Based on the reported MAUDE rates for this six year period, the event rates were 0.17% anterior and 3.01% posterior.

The event rates from the published literature for pedicle and lateral mass screws in the cervical spine are within range of these MAUDE rates for current Class II spinal implants. The published literature and MAUDE data identify the risks and support the classification of lateral mass and pedicle screws in the cervical spine as Class II devices.

5. PROPOSED REGULATORY CONTROL

The Petition's review of the published literature and MAUDE data for the pedicle and lateral mass screws in the cervical spine demonstrates that the risks can be defined, that the risk of illness or significant injury is low and that the types of events are consistent with other Class II uses in the spine. Class II spinal implants are currently regulated by general and special controls. As described below, these controls are adequate to provide reasonable assurance of safety and effectiveness. Further clinical evidence regarding the safety and effectiveness of lateral mass and pedicle screws is not required.

5.1. GENERAL CONTROLS

General controls include manufacturing establishment registration, Quality System Regulation, provisions regarding adulteration and misbranding, record keeping, and reporting of adverse events.

5.2. SPECIAL CONTROLS

In addition to general controls, this Petition recommends use of special controls to mitigate any risk associated with use of pedicle and lateral mass screws in the cervical spine. These special controls include performance standards already recognized by FDA (i.e., material, mechanical testing, and biocompatibility), training and other appropriate labeling information. Subsequent to the down classification of pedicle screws, special controls were implemented with FDA's Guidance for Industry and FDA Staff: Spinal System 510(k)s (May 3, 2004 which superseded a September 27, 2000 guidance). The proposed special controls should be evaluated to determine if they can control, not eliminate, such risks to health.

Material Standards

The metals used in the manufacture of pedicle and lateral mass screws have a long history of safe use in humans. In addition, relevant ASTM material standards provide the chemical, mechanical and metallurgical requirements for these materials, when they are to be used in the manufacture of surgical implants.

Biocompatibility Standards

Biocompatibility of devices comprised of alternative or new materials can be assured through ISO 10993, Biological Evaluation of Medical Devices and through adherence to existing material standards. Compliance with these standards and/or ISO 10993 will provide reasonable assurance of the safety of material used in devices.

Mechanical Testing Standards

The static and dynamic (fatigue) mechanical performance of pedicle and lateral mass screws can be addressed with test standards that have been previously applied with the evaluation of spinal devices as follows:

ASTM F-1717(2004) Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model.

ASTM F-1798-97(2008) Standard Guide Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants.

ASTM F2706-08 Standard Test Methods for Occipital-Cervical- and Occipital-Cervical-Thoracic Implant Constructs in a Vertebrectomy Model

Training

Training and education is currently offered by the major orthopedic and spinal societies ("surgeons training surgeons"). In addition, product manufacturers can provide training regarding specific product use and provide surgical techniques to assist with implantation of their specific systems. These are the same training mechanisms as currently established for other Class II spinal devices.

Labeling

With the Petition, the following indication for use is recommended:

> Lateral mass and pedicle screw systems are intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion during bone graft healing and fusion mass development and/or to restore the integrity of the spinal column even in the absence of fusion for a prolonged period for the following acute and chronic instabilities of the cervical spine (C1 to T3 inclusive): trauma, including spinal fractures and/or dislocations; instability or deformity; pseudarthrosis or failed previous fusions; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability; and tumors. Spinal screw fixation is achieved with posterior pedicle and lateral mass screws implanted from C1 to T3 levels inclusively.

These indications are similar to use of pedicle screws in the thoracic, lumbar and sacral spine with a Class II designation.

The Guidance for Spinal System 510(k)s (May 2004) provides examples of additional labeling specific to spinal implants. Labeling requirements are designed to direct use and inform users to limit risks. Currently, the Guidance for Spinal System 510(k)s includes the warning and precaution identified below. With this Petition, we recommend elimination of the warning that follows:

> ``Warning: The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral

spine secondary to severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra, degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). The safety and effectiveness of these devices for any other conditions are unknown. ``

With the Petition, the following precautions are recommended:

``Precaution: The implantation of cervical lateral mass and pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of these screws as this is a technically demanding procedure presenting a risk of serious injury to the patient.``

"Precaution: Pre-operative planning for implant of cervical lateral mass and pedicle screw implants should include review of radiographs, CT and/or MRI imaging to evaluate the patient's anatomy, transverse foramen and the course of the nerve roots and vertebral artery. If any findings would compromise the placement of lateral mass or pedicle screws, other surgical methods should be considered. In addition, use of intra-operative imaging should be considered to guide and/or verify device placement, as necessary".

In addition, labeling requirements are discussed in various FDA guidance documents including the Device Labeling Guidance (#G91-1 (Blue Book Memo). This guidance describes the contents of the label including indications, contraindications, precautions and warnings. The labeling for these devices includes the caution: Federal law restricts this device to sale by or on the order of a physician.

5.3. RISK MITIGATION

The potential risks with lateral mass and pedicle screws and spinal surgery in the cervical spine, as well as the regulatory controls that mitigate the risk, follow below. As identified in the published literature, risks to health presented by the devices include malposition, implant loosening, device breakage, disassembly, malfunction, bone fracture, graft settling/displacement, loss of correction and pseudarthrosis. Malposition may result in vertebral artery, spinal canal or nerve injury. The same risks and regulatory controls currently apply to anterior and posterior cervical spine implants for Class II indications.

Table 7. Potential Risks and Regulatory Controls

Device-Specific Adverse Events	Material Standards	Mechanical Testing	Biocompatibility Standards*	Training	Labeling	QSR General Controls
Malposition	--	--	--	Yes	Yes	--
Implant loosening	-	Yes	Yes	Yes	Yes	--
Device breakage	Yes	Yes	--	Yes	Yes	Yes
Disassembly	Yes	Yes	--	Yes	Yes	--
Malfunction-Device	Yes	Yes	--	Yes	Yes	Yes
Bone Fracture	--	--	--	Yes	Yes	--
Graft settling/ displacement	--	--	--	Yes	Yes	--
Loss of correction	Yes	Yes	Yes	Yes	Yes	--
Pseudarthrosis	Yes	Yes	Yes	Yes	Yes	--
Other Adverse Events	**Material Standards**	**Mechanical Testing**	**Biocompatibility Standards***	**Training**	**Labeling**	**QSR General Controls**
Bleeding/Vascular Injury	--	--	--	Yes	Yes	--
Neurologic injury	-	-	-	Yes	Yes	-
CSF leak	--	--	--	Yes	Yes	--
Wound	-	-	-	Yes	Yes	-
Infection	-	-	-	Yes	Yes	-
Skin irritation	-	-	Yes	Yes	Yes	-
Cardiac	-	-	-	Yes	Yes	-
Respiratory	-	-	-	Yes	Yes	-
Revision surgery	Yes	Yes	Yes	Yes	Yes	--
Death	Yes	Yes	Yes	Yes	Yes	--

*New materials

6. RATIONALE FOR RECLASSIFICATION

To classify lateral and pedicle screws to Class II, responses to the FDA's Classification (21 CFR 860.123(a)(4)) and Supplementary Data (21 CFR 860.123(a)(3)) Sheets with rationale follow.

6.1 CLASSIFICATION QUESTIONAIRE

Question	Response	Rationale
Is the device life sustaining?	No	Device provides spinal stabilization
Is the device for a use which is of substantial importance in preventing impairment of health?	Yes	Outcomes may include stability with fusion, temporary stabilization, pain control, palliative care, relief and/or prevention of neurologic deficit.
Does the device present a potential for unreasonable risk of illness or injury?	No	Screw placement accuracy rates in the cervical spine were high, and the results were comparable to screw placement accuracy in the thoracic and lumbar spine. When screws were malpositioned, the risk of serious long term consequences was low. The rate of device events was low.
Is there sufficient information to determine that general controls are sufficient to provide reasonable assurance of safety and effectiveness?	No	If "yes", Class I.
Is there sufficient information to establish SPECIAL CONTROLS in addition to GENERAL CONTROLS to provide reasonable assurance of safety and effectiveness?	Yes	If "yes", Class II. Guidance document, performance standards, testing guidelines, training and labeling If "no", Class III.
Is a performance standard needed to provide reasonable assurance of the safety and effectiveness for a Class II or Class III device?	Not applicable	Performance standards for materials and relevant guidance documents exist.

6.2 SUPPLEMENTAL DATA SHEET

Question	Response
Indications	Lateral mass and pedicle screw systems are intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion during bone graft healing and fusion mass development and/or to restore the integrity of the spinal column even in the absence of fusion for a prolonged period for the following acute and chronic instabilities of the cervical spine (C1 to T3 inclusive): trauma, including spinal fractures and/or dislocations; instability or deformity; pseudarthrosis or failed previous fusions; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability; and tumors. Spinal screw fixation is achieved with posterior pedicle and lateral mass screws implanted from C1 to T3 levels inclusively.
Identifications of risks to health presented by the device	Risks to health presented by the devices include malposition, implant loosening, device breakage, disassembly, malfunction, bone fracture, graft settling/displacement, loss of correction and pseudarthrosis, Malposition may result in vertebral artery, spinal canal or nerve injury.
Recommended Advisory Panel Classification	II
If device is an implant or is life-sustaining and has been classified in a category other than Class III, explain fully the reasons for the classification with supporting documentation and data.	Class II designation of pedicle and lateral mass screws for cervical use is consistent with the current regulation of other spinal implants for the same intended use.
Summary of information including clinical experience or judgment upon which classification recommendation is based	Evidence from the published literature and FDA MAUDE databases for pedicle/lateral mass screw use in the cervical spine, as well as pedicle screw use for more than 40 years and indications that have been Class II for more than 10 years.
Identification of any needed restrictions on the use of the device	Restrict use of the device to sale by or on the order of a physician and use only by experienced surgeons with specific training in the use of pedicle and lateral mass screws in the cervical spine.

7. CONCLUSIONS

FDA is required to classify and reclassify devices into the lowest class that can reasonably assure the safety and effectiveness of the device. With the classification process, it is not necessary to show that the generic devices are safe and effective, as is done in a premarket approval (PMA), to classify a type of device to Class II. While both PMA and classification activities require judgments about safety and effectiveness, the basis for the judgments is different. A PMA focuses on one specific device and the review assumes that there is little known about the device and thus a complete assessment of all aspects of safety and effectiveness of each specific device is required. For classification, the question is whether the knowledge of the category of devices is adequate for reclassification. In general, the evidence needs to support judgment that devices within the generic type can, and generally do, safely achieve their intended use. Secondly, the evidence needs to provide information as to how the devices may fail to be effective or safe, and how such failures can be minimized or avoided by the application of available regulatory controls. Devices may have risks that can possibly lead to a serious injury; however, this does not mean that the device presents unreasonable risk but rather how these risks can be eliminated or reduced with regulatory controls.

Class I or III classifications are not appropriate for lateral mass and pedicle screw use in the cervical spine. The regulatory controls of Class I devices (general controls only) do not allow for device characterization and testing with premarket clearance and the additional controls of Class III devices (years of clinical study before market approval, premarket approval and reporting, premarket inspection) are not consistent with the potential risk of these devices or the classification of similar devices currently designated Class II devices with Special Controls.

Class II is an appropriate classification as it is defined as a low to moderate risk device with known potential risks, which can be effectively mitigated with Special Controls such as guidance documents and labeling. The published literature provides adequate information to demonstrate the effectiveness and to define the potential risks of these devices, which may be characterized by a generic description.

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NOTE: Bolded articles are updates since the November 2011 petition.